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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/540,999

06/28/2005

Hesham Morsi

Morsi-01

9037

7590 05/29/2008  
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EXAMINER
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GANESAN, SUBA

ART UNIT	PAPER NUMBER
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3774

MAIL DATE	DELIVERY MODE
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05/29/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/540,999	<b>Applicant(s)</b> MORSI, HESHAM	
	<b>Examiner</b> SUBA GANESAN	<b>Art Unit</b> 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4-10,12-42,45-47,50-52 and 55-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-10,12-42,45-47,50-52,55-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments with respect to claims 1,4-10, 12-42,45-47,50-52,55-57 have been considered but are moot in view of the new ground(s) of rejection.

### *Claim Objections*

1. Claim **4** is objected to because of the following informalities: The term "non-linear longitudinal axis" is unclear since convention dictates that an axis is linear. Appropriate correction is required.
2. Claim 13 objected to because of the following informalities: Claim 13 depends from cancelled claim 11. Appropriate correction is required.

### *Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims **1, 4-6,8-10,12-19, 22-33, 38, 42, 45-47, 50, 55-57** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogers et al. (U.S. Pat. No. 5,607,468) in view of Holman et al (U.S. Pat. No. 6,319,276), further in view of Guiset (U.S. Pat. No. 4183102).
5. Rogers discloses an inflatable tubular graft with a first outer wall **80** and a second inner wall **70** with at least one fused juncture creating fluid impermeable seals and fluid

communicating passages (see fig. 11 for example) and a valve to inflate the graft (col. 2 lines 54-60). However, Rogers lacks a juncture configured as a band around the circumference of the graft.

6. Holman teaches the design of circumferential bands in a graft resulting in circumferential channels that create inflatable graft prosthesis. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the fused junctures of Rogers with a circumferential orientation as taught by Holman as an alternative means of creating inflatable graft prosthesis.

7. Rogers and Holman lack radially oriented web reinforcements. Guiset teaches the use of non-elastic web reinforcements 47, 49 (see fig. 8-9, and col. 6 lines 39-65) resulting in a reinforced inflation chamber. It would have been obvious to one of ordinary skill in the art to provide the prosthesis of Rogers and Holman with include non-elastic web reinforcements as taught by Guiset, the motivation to combine being: creating a support network for the inflatable chambers that further defines flexibility of the graft. Examiner considers the tapering of the web reinforcement to be a matter of obvious design choice if the inflation chamber of the prosthesis is tapered. A tapered or at least rounded inflation chamber is provided by the combination of Rogers and Holman.

8. The resulting combination is considered to be fully capable of serving as a graft for placement through tortuous, narrow or stenotic cerebral blood vessels. Alternatively, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the resulting prosthesis sized for cerebral blood vessels,

since such a modification would have involved a mere change in the size of the prosthesis. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

9. Rogers further lacks disclosure of the outer wall dimension after inflation. However, a diameter of less than 10mm would be obvious to one of ordinary skill in the art since the object of the vascular graft is to support a vascular lumen. Therefore dimensions of the vascular graft mirror dimensions of the vasculature in which the graft is designed to be used, which encompasses an outer wall dimension of less than 10mm.

10. With respect to claim 4, as best understood, a fused juncture defines a non-linear longitudinal length of the graft (see fig. 7). The inner and outer walls are comprised of materials having different elasticity (col. 1 lines 25-34), specifically PTFE (col. 2 lines 63-64). A fluid fills the interstitial space (col. 2 lines 54-60). The graft has a first and second end with different diameters (see fig. 7). With respect to claims 17-18, the intended use of the device carries no patentable weight in the absence of distinguishing structure; the device of Rogers is fully capable of treating aneurisms and atherosclerosis (col. 1 lines 20-23). The outer wall of the Rogers graft forms a corrugated surface while the inner wall is smooth (fig. 11). A method is disclosed of using a catheter **44** to deliver and inflate the graft (col. 3 lines 24-39). The graft reinforces the blood vessel wall (fig. 6). The inflated graft can be used with a diseased vessel wall (col. 1 lines 21-23), which inherently isolates the diseased vessel wall from the lumen.

11. With respect to claim 33 and 38, Rogers discloses inserting a two walled graft using a catheter, the two walled graft having a fluid seal at each end (note that fluid cannot permeate outside the graft wall on either end, which is what examiner is considering to be a fluid seal at each end), a plurality of connectors radially oriented (note that examiner is considering the fused portions of the first and second walls to be 'connectors', and the fact that they are arranged around the circumference of the graft to be 'oriented in a substantially radial direction), and a valve to regulate inflation fluid (fig. 1, col. 3 lines 24-40). With respect to claim 45-47 the graft is of a pre-selected inflatable dimension and shape (fig. 2) and can have varying length connectors (fig. 7).

12. Claims **7,34-37,39-41** 35 U.S.C. 103(a) as being unpatentable over Rogers et al. (U.S. Pat. No. 5,607,468) in view of Holman et al (U.S. Pat. No. 6,319,276) and Guiset (U.S. Pat. No. 4183102) as applied above, further in view of Lazim (U.S. Pat. No. 5330528).

**13.** Rogers in view of Holman and Guiset is explained supra, including a graft made of PTFE or ePTFE (col. 2 line 61-col. 3 line 3), which is a material used in applicants invention. Since Rogers has the specific material disclosed, it is inherent that the graft of Rogers will include non-elastic material. In the alternative, Rogers is silent as to the elastic properties of the inflatable graft. Lazim teaches the use of flexible but inelastic materials in inflatable grafts for the purpose of controlling the contour and size of the graft (col. 6 lines 22-27). Therefore it would have been obvious to one of ordinary skill in

the art to combine the teaching of non-elastic materials from Lazim with the graft of Rogers for the purpose of creating a graft with a pre-determined shape and contour.

14. Claims **20-21** and **51-52** are rejected under 35 U.S.C. 103(a) as being unpatentable over Rogers et al. (U.S. Pat. No. 5,607,468) in view of Holman et al (U.S. Pat. No. 6,319,276) and Guiset (U.S. Pat. No. 4183102) as applied above, further in view of Samson (U.S. Pat. No. 5370691).

15. Rogers is explained supra. However, Rogers is silent as to the inflation media used to expand the graft. Samson teaches the use of HEMA, a curable monomer, to inflate a vascular support (col. 5 lines 15-31). Therefore it would have been obvious to one of ordinary skill in the art to use a curable monomer as taught by Samson for the purpose of expanding the graft and creating a firm vascular support.

### ***Conclusion***

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUBA GANESAN whose telephone number is (571)272-3243. The examiner can normally be reached on M-F 7-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. G./

Examiner, Art Unit 3774

/William H. Matthews/

Primary Examiner, Art Unit 3774



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